ANSWERS TO THE
MOST FREQUENTLY ASKED QUESTIONS

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CONTINUING EDUCATION REQUIREMENTS FOR LICENSE RENEWAL

CITE: TN Regulation 1140-5

Rule 1140-5-.01 requires that **thirty(30) contact hours of pharmaceutical continuing education** shall be completed by every pharmacist licensee for renewal of the biennial license Points to be considered.

› Fifteen (15) contact hours of the CE must be obtained from **"live"** contact programs **All of these hours must be ACPE approved and designated "live" by the course number.** The course number must contain an "L" *for "live" or "C" for combination in the space occupied by the third digit from the right end of the number. If the CE designation is a "C" the actual number of live hours must be identified on the certificate.* All thirty hours may be "live".

› Fifteen contact hours may be obtained from other sources including correspondence courses and articles in professional journals. At least nine (9) of these contact hours must be ACPE approved. **You may have no more than six (6) contact hours of board approved CE that is not ACPE approved.**

› A pharmacist will not be required to complete any CE during a biennial cycle if the pharmacist presents proof that during **all or part of the license cycle** that the pharmacist was enrolled in a recognized academic program pursuing an advanced degree. Examples of advanced degrees are contained in Rule 1140-5-.01(2) fellowship or residency is considered an advanced curriculum.

› The signed Affidavit must be provided to the board office with a list of courses and the number of hours for each one.

› A license will not be renewed until proof of the CE is submitted. A $50.00 penalty may be assessed for failure to comply.

› Falsification of any documents renders the licensee subject to disciplinary action.

PRESCRIPTION WRITING FORMATS FOR NURSE PRACTIONERS AND PHYSICIAN ASSISTANTS

This year, the Tennessee General Assembly passed Public Chapter 259, which standardizes the prescription-writing format for Nurse Practitioners and Physician Assistants.

Every prescription issued by a physician assistant or nurse practitioner shall be entered in the medical records of the patient and shall be written on a preprinted prescription pad bearing the name, address, and telephone number of the supervising physician and of the physician assistant or nurse practitioner, and the physician assistant or nurse practitioner shall sign each prescription so written.

Where the preprinted prescription pad contains the names of more then one (1) physician, the physician assistant or nurse practitioner shall indicate on the prescription which of those physicians is the primary supervising physician by placing a check mark beside or a circle around the name of that physician.

Physician Assistant or Nurse Practitioners are no longer required to sign the name of their supervising physician.

The name of the prescriber (physician assistant or nurse practitioner) should be on the dispensing label of the prescription rather than the name of the supervising physician.

CONTROLLED SUBSTANCE PRESCRIPTIONS VIA FACSIMILE

SCHEDULE II CITE: CFR 1306.11

A properly prepared prescription for a controlled substance in Schedule II may be transmitted from the prescriber or the prescriber's agent to the pharmacy and the facsimile prescription serves as the original prescription in three (3) circumstances.

1. The prescription is to be compounded for the **direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.**
2. The prescription is for **a resident of a Long Term Care Facility (LTCF).**
3. The prescription is for a patient who is a **patient of a Medicare or state licensed Hospice agency**. The pharmacist will note on the prescription that the patient is a hospice patient.

Prescriptions received by facsimile from the patient, caregiver, or any source other than the prescriber or the prescriber's agent are for information purposes only. The pharmacist must be presented with the prescription prior to filling the prescription. All records must be maintained for two years.

SCHEDULES III, IV, AND V.CITES CFR 1306.21

A pharmacist may dispense directly a prescription for a drug in controlled substance in Schedules III, IV, and V. pursuant to a facsimile of a written prescription transmitted by the prescriber or the prescriber's agent to the pharmacy. Prescriptions received via facsimile from the patient, caregiver, or any source other than the prescriber or the prescriber's agent are for information purposes only. All records must be maintained for two years.

WHAT INFORMATION CAN BE CHANGED ON THE FACE OF A SCHEDULE II PRESCRIPTION?

A memorandum dated December 7, 1999 authored by Larry Houck of the DEA Office of Diversion Control addressed what information may be changed on a Controlled Substance Schedule II prescription.

> "The majority of changes can be made only after the pharmacist contacts the prescribing practitioner. After consultation with the prescribing practitioner, the pharmacist is permitted to change the patient's address, drug strength, drug quantity, and directions for use. The pharmacist is permitted to make information additions that may be provided by the patient or bearer such as the patient's address, and such additions should be verified. The pharmacist may also add the dosage form to the prescription order after verification with the prescribing practitioner."

> "The pharmacist is **never** permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law) or the prescriber's signature. These types of changes challenge the necessity of the original prescription and would require a new prescription form the prescribing practitioner."

LTCF GUIDELINES FOR EMERGENCY KITS

With recognition of the DEA's statement of Guidelines for Emergency Kits in Long Term Care Facilities (LTCF), Appendix R, the following policy is adopted.

1. SOURCE OF SUPPLY:

   - All controlled substances contained in the emergency kit must be supplied by the duly licensed and currently DEA registered provider pharmacy designated by the LTCF.

2. SECURITY SAFEGUARDS, ACCOUNTABILITY AND RECORDKEEPING, and, ADMINISTRATION OF CONTROLLED SUBSTANCES:

   - The access, storage, and administration of the controlled substances contained in the emergency kit must meet the requirements of Tennessee Board of Pharmacy Regulation 1140-4-.09

   - Controlled Substance, Schedule II drugs in the emergency kit must be stored in a cabinet or other structure that provides a double locked secure system.

   - The contents of the emergency kit is specifically limited to the following:

   (a) A maximum of two (2) dosage units each of any two CS Schedule-II Injectable Narcotic Analgesic.

   (b) A maximum of two (2) dosage units each of any two CS Schedule II Immediate Acting Oral Narcotic Analgesic.

   (c) A maximum of four (4) dosage units each of any two (2) CS Schedule III, IV, or V Oral Narcotic Analgesic.

   (d) A maximum of two (2) dosage units each of any two CS Injectable Anti-Seizure medication. *November 19, 2002*

PARTIAL FILLING ON PRESCRIPTIONS FOR CONTROLLED SUBSTANCES

SCHEDULE II CITE: CFR 1306.13

The partial filling of prescriptions for controlled substances in Schedule II is permitted under the following scenarios.

1. If the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription. The pharmacist makes a notation of the quantity supplied on the face of the prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion cannot be supplied within the 72 hour period, the pharmacist shall notify the prescriber.

2. If the prescription is for a patient in a **Long Term Care Facility (LTCF**), or

3. If the prescription is for a patient with a **documented terminal illness**.

The pharmacist must record on the prescription the notation of **"terminally ill" or "LTCF patient."** The prescription then may partially fill up to the total quantity prescribed or up to a period of 60 days. There is no limit on the number of partial fills. Each partial fill must be documented on the back of the original prescription or in a computerized system. These records must be maintained for a period of two years.

SCHEDULES III, IV, AND V. CITE: CFR 1306.23

The partial filling of prescriptions for controlled substances in Schedules III, IV, and V is permitted as long as the **total quantity dispensed in all the partial fillings does not exceed the total quantity prescribed and no**

dispensing occurs after 6 months after the date the prescription was issued. These records must maintained for two years.

TIME LIMITS ON PRESCRIPTIONS FOR CONTROLLED SUBSTANCES

SCHEDULE II CITE: TN Regulation 1140-3-.03(6)(d.)

There is no time limit identified in federal law. You may fill a prescription for a controlled substance listed in Schedule II up to one year from the date that the prescription was issued as cited in the rules of the Tennessee Board of Pharmacy.

SCHEDULES III, and IV. CITE: CFR 1306.22

Prescriptions for controlled substances in Schedules III, and IV cannot be filled or refilled more than six (6) months after the date on which the prescription was issued.

SCHEDULE V CITE: TN Regulation 1140-3-.03(6)(d.)

There is no cite in federal law concerning prescriptions for controlled substances in Schedule V. Therefore the Tennessee Regulation would apply. You may fill a prescription for a controlled substance listed in Schedule V up to one year from the date that the prescription was issued.

CAVEAT

Pharmacists should understand that the interpretations listed above are solely the opinion of the Tennessee Board of Pharmacy. While these opinions are based on solid and defensible research, this should be considered as an opinion.

TRANSFER OF CONTROLLED SUBSTANCES BETWEEN REGISTRANTS

CITE: CFR 1307.11

SCHEDULE II
You may sell or distribute to another pharmacy or DEA registered prescriber (physician, dentist, etc.) **via the DEA 222 form only. You may not accept a prescription for office use.**

SCHEDULES III, IV, and V.
You may sell or distribute to another pharmacy or DEA registered prescriber via a duplicate invoice. The invoice must contain the name, address, and DEA number of both the seller and the buyer. In addition, the invoice must contain the date of sale, the name, strength, metric quantity, and dosage form of the drug sold. These records must be kept available for two years.

Sales may not exceed 5% of the total number of dosage units of all controlled substances distributed and dispensed during the same calendar year

INSULIN AND SYRINGE SALES

CITE: TN Regulation 1140-3-.12

Tennessee Board of Pharmacy Rule 1140-3-.12 (4) addresses the storage, sale and delivery of insulin preparations and states as follows:

> "All insulin preparations must be stored in an area not accessible to the public, and shall be sold only by a pharmacist, pharmacy intern, or a pharmacy technician under the direct supervision of a pharmacist."

Rule 1140-3-12(3) addresses the storage, sale, and delivery of syringes and devices utilized for injection and states as follows:

> "Instruments and/or devices intended for the injection of any substance through the skin shall be stored in an area not accessible to the public, and shall be sold only on proof of medical need by a pharmacist, pharmacy intern, or a pharmacy technician under the direct supervision of a pharmacist."

Technicians do not need to be certified to sell insulin or syringes but must be under the direct supervision of the pharmacist. These regulations are permissive in nature and are not mandated by the board. The pharmacist on duty has the responsibility of making any decision as to who can sell insulin and syringes.

POWER OF ATTORNEY TO PURCHASE CONTROLLED SUBSTANCES

CITE: CFR 1305.07

Any DEA registered purchaser **may authorize one or more individuals** to obtain or execute order forms on their behalf by executing a power of attorney (POA) for each individual. Some points to remember.

- The individual receiving the POA may or may not be located at the registered location.
- The individual does not have to be a pharmacist.
- The POA shall be signed by the same person who signed the most recent application for registration and by the individual receiving the POA.
- The POA should be filed with the executed order forms of the purchaser and be available for inspection.
- The POA shall be retained for the same time period as any order form bearing the signature of the person named on the POA. This is a minimum of two years.
- The POA may be revoked at any time and the Notice of Revocation should be placed in the same file as the POA.
- The suggested forms for the POA and Notice of Revocation are in the cited chapter of CFR.

TRANSFER BETWEEN PHARMACIES OF PRESCRIPTION INFORMATION FOR SCHEDULES III, IV, AND V CONTROLLED SUBSTANCES FOR REFILL PURPOSES.

(EXCHANGE OF COPIES)
CITE: CFR 1306.25

(A) "The transfer of original prescription information (a copy of a prescription) for a controlled substance listed in Schedules III, IV, and V for the purpose of refill dispensing is permissible between pharmacies on a **one time basis only.** However, **pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization."**

Transfers are subject to the following requirements:

1. The transfer is communicated directly between two **licensed pharmacists** and the transferring pharmacist records the following information:

   (I) Write the word "VOID" on the face of the invalidated prescription.
   (II) Record on the reverse of the invalidated prescription the name, address, and **DEA registration number** of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.
   (III) Record the date of the transfer and the name of the pharmacist transferring the information.

(B) The pharmacist receiving the transferred prescription information (the copy) shall reduce to writing the following:

   (1) Write the word ***"TRANSFER"*** on the face of the transferred prescription.
   (2) Provide all information required to be on a prescription pursuant to 21 CFR 1306.05 and include:

      (I) Date of issuance of original prescription.
      (II) Original number of refills authorized on original prescription.
      (III) Date of original dispensing.
      (IV) Number of valid refills remaining and date(s) and locations of previous refill(s).
      (V) Pharmacy's name, address, **DEA registration number**, and prescription number from which the prescription information was transferred.
      (VI) Name of the pharmacist who transferred the prescription.
      (VII) Pharmacy's name, address, **DEA registration number**, and prescription number from which the information was originally filled.

   (3) The original and transferred prescription(s) must be maintained for a period of two years from the **date of the last refill.**

(C) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral.

(D) The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing state or other applicable law.

CITE: TN Regulation 1140-3-.03(7)(c)

"The transferee informs the patient that the original medical or prescription order has been canceled at the pharmacy practice site from which it was obtained."

PATIENT COUNSELING

MANDATORY COUNSELING ON NEW PRESCRIPTIONS
CITE: Rule 1140-3-.01(1)(a.)

"**Upon receipt of a medical or prescription order and following a review of the patient's record, a pharmacist shall personally counsel the patient or caregiver face to face if the patient or care giver is present**. If the patient or caregiver is not present, a pharmacist shall make a reasonable effort to counsel through alternative means."

OFFER TO COUNSEL ON REFILLS
CITE: Rule 1140-3-.01(1)(f.)

"Upon the receipt of a request for a refill of a medical or prescription order, a pharmacist or a person designated by the pharmacist shall offer for the pharmacist to personally counsel the patient or caregiver."

Counseling is not required unless requested by the patient or deemed necessary in the professional judgment of the pharmacist.

Counseling is not required when the patient refuses counseling.

PENALTIES FOR VIOLATIONS

First Offense	**Second Offense in the same 12 Month Period**	**Third Offense in the same 12 month period**
Pharmacist $100. Pharmacy $500.	Pharmacist $100. - Letter of Reprimand Pharmacy $500.- Letter of Reprimar	Pharmacist $100. & Informal Conference Pharmacy $500. & Informal Conference

COUNSELING AREA CITE: Rule 1140-1-.12(2)

All pharmacies must have a consultation area which offers sufficient privacy to the patient. The board does not specify the dimensions, design, location, or space requirements for this area. The decision is left up to you! Construction could be very simple or quite elaborate depending on your individual needs. Privacy is the most important factor.

PRESCRIPTIONS FROM OUT OF STATE AND FOREIGN PHYSICIANS

There are no federal or state laws that prohibit the filling of a prescription from an out of state prescriber in the State of Tennessee. This includes prescriptions from prescribers in the trust territories of Puerto Rico and the Virgin Islands.

Prescriptions for Controlled Substances must be written in accordance with the requirements of CFR 1306.05 and the pharmacist assumes a corresponding liability to make sure that the prescription meets these requirements.

Prescriptions from prescribers and practitioners other than cited in the first paragraph are not considered legal in the United States and should not be filled.

PHARMACY TRANSFER AND CLOSING

AT LEAST 14 DAYS OR MORE IN ADVANCE OF TRANSFER OR CLOSING

- As per CFR §1307.14, notify the regional DEA office by **registered or certified return receipt letter** of the (1) name, address, registration number and the type of business, (2) the name, address, registration number and type of business of the company or person acquiring the controlled substances, and (3) the date that the transfer will occur.
- Arrange with a DEA authorized return goods reverse distributor(list available from the DEA) to return all outdated merchandise, or if not using a reverse distributor;
- Contact the Board of Pharmacy for the proper forms for controlled substance drug destruction.

THE DAY OF THE TRANSFER OR CLOSING

All controlled substances must be (1) returned to manufacturer or distributor, (2) transferred to another DEA registered pharmacy, or (3) destroyed by an authorized representative of the Board of Pharmacy (drug destruction can be done at a later date)

Transfer and Return

- Schedule II drugs must be done on a DEA Form 222.
- Schedule III, IV, and V drugs can be done by duplicate invoice showing the (1) name, address and DEA registration number of both parties, (2) the name, strength, quantity and dosage form of the drugs, and (3) the date of the transaction.
- Destroy all legend drugs that are not controlled substances and are not returned or transferred by the Pharmacist in Charge.
- Dispose of all legend and OTC drugs in such a manner as to prevent any accidental access by the public.

AS SOON AS POSSIBLE AFTER CLOSING

- Mail (A) copy 2 of DEA form 222, (B) DEA registration certificate,(C) all unused DEA Form 222, and (D) a signed letter containing the (1) date of closing, (2) the disposition of the controlled substances, and (3) the location where copy 3 of the DEA form 222 and all other DEA required records (i.e.: biennial inventory and receiving records, etc.) will be kept for the next 2 years to:
- Drug Enforcement Administration Room 500, 801 Broadway, Nashville, TN 37203 (615) 736-2559

- Mail (A) the state license card and (B) a letter containing (1) the date of closing, (2) the disposition of the controlled substances and legend drugs, and (3) the location where all records will be kept to:

  The Tennessee Board of Pharmacy
  500 James Robertson Parkway
  Nashville, TN 37243-1149
  (615) 74-2718

- Please contact a Reverse Distributor to arrange for the destruction of any controlled substances.

PHARMACY TECHNICIAN DUTIES AND RATIOS

CITE: TN Regulation 1140-2-.02

The Pharmacist in Charge is responsible for compliance with the technician provisions. A technician must be in the presence of and under the supervision of a pharmacist. All technicians may perform a number of functions outlined in the rule including;

- Accept a refill order from a patient, practitioner, or practitioner's agent.
- Obtain and input patient or prescription order data.
- Prepare and affix a prescription label.
- Retrieve, count, stock, measure, order, and place drugs in containers.
- Affix auxiliary labels.
- Prepackage and label drugs for future dispensing.
- Prepare unit dose carts for pharmacist review.
- Deliver and transport drugs and prescriptions under established protocol.

Only Certified Technicians may.

- Receive new or transferred (copies) oral medical and prescription orders subject to pharmacist approval.

RATIOS

- Two(2) technicians may be supervised by one (1) pharmacist, however the ratio maybe increased to three(3) technicians supervised by one (1) pharmacist if at least one(1) of the technicians is certified.

GENERAL REQUIREMENTS.

Technicians must
- Wear appropriate identification.
- Display the certificate or evidence of certification
- Display his/her Registration Certificate

The Pharmacist-in-Charge must maintain a roster or registry of all individuals performing the functions of a technician. The registry does not have to be displayed and may be kept in electronic or computer format and be readily retrievable.

Interns working at the pharmacy are not considered technicians.

"PRN" PRESCRIPTIONS

CITE: TN Regulation 1140-3-.03 (6)

(D) "If a prescription contains a statement that during any particular time it may be refilled at will, the order shall be refilled in strict conformity to dosage directions, with the exception that it may not be refilled after the expiration of time specified or one (1) year from the date the order was originally issued or dispensed, whichever comes first."

QUININE SULFATE FOR LEG CRAMPS

On February 22, 1995, the Food and Drug Administration (FDA) issued a final rule requiring drug manufacturers to stop manufacturing and marketing over-the-counter (OTC) quinine sulfate for nocturnal leg muscle cramps. FDA stated the ruling was due to a lack of adequate data to establish a general recognition of safety and effectiveness of quinine for this indication.

As a result of the FDA rule, all OTC quinine sulfate products with a label indication for nocturnal leg cramps are now considered misbranded products. Pharmacists providing such products to their patients would be violating federal law.

Pharmacists may continue to dispense quinine prescriptions for malaria, which remains the only approved indication for the drug. Pharmacists should contact physicians who continue to treat nocturnal leg cramps via prescription and inform them that the FDA has published the preceding rule. Decisions concerning quinine therapy should be accurately noted in the patient medication records.

METHADONE

CITE: CFR 1306.07-
Administering or dispensing of narcotic drugs.

Methadone may be used for any legitimate medical purpose. An outpatient prescription for Methadone or any other narcotic **may not be dispensed if the prescription will be used to treat or maintain addiction.**

Methadone may be provided in the hospital to treat or maintain addiction or detoxify an addict when used as an incidental adjunct to medical or surgical treatment of conditions other than addiction.

In an emergency, a physician who is not specifically registered to conduct a narcotic treatment program, may obtain a one day supply of Methadone or other C-II narcotic drugs via a DEA 222 form to administer (not dispense) to a person for the purpose of relieving acute withdrawal symptoms while making arrangements for treatment. Not more than one day's medication may be administered for the person's use at one time. This emergency treatment cannot be carried out for more than three days and may not be renewed or extended.

SUBSTITUTION AND FORMULARY PRODUCT SELECTION

CITE: T.C.A. § 53-10-202, § 53-1--203, § 53-10-204, § 53-10-205, § 53-10-206

When substituting on a prescription, developing a formulary of substitutable products, or having prescription pads printed please remember the following.

- Prescription blanks must have two lines for the prescriber signature. The board suggests the following format.

  Dispense as Written _____ Signature

  Substitution Allowed _____ Signature

- Any prescription written on a prescription that does not conform to the two line format may be substituted unless the prescriber indicates "dispense as written."
- Any drug substituted must be an "A" rated entity in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The best sources of this information other than the actual Orange Book are the manufacturer or supplier of the product. You may also visit the electronic Orange Book at the FDA website at www.fda.gov/cder and search for this information.
- Pharmacists are encouraged to produce a prescription label in the following format.

  " Generic name of drug " substituted for " brand name of drug"

WEIGHT LOSS DRUGS

The following drugs are listed in The Board of Medical Examiner's Rule 0880-2-.14. Amphetamines, Phenmetrazine, Benzphetamine, Chlorphentermine, Phendimetrazine, Diethylpropion, and Mazindol. You should not accept a prescription for these drugs from a physician licensed in Tennessee for the treatment of obesity. Pursuant to Board of Medical Examiners Rule 0880-2-.14, (Xenical ™) Phentermine, and Sibutramine (Meridia ™) are the only prescription legend drugs that may be prescribed by a Tennessee Physician for the treatment of obesity. Orlistat should be treated as any other prescription legend drug. You may accept prescriptions for Orlistat from an appropriate prescriber by phone, fax, or in writing. Orlistat may be refilled in strict conformity with dosage directions up to the number of refills indicated and up to a period of one-year from the date the prescription was originally issued or dispensed.

Phentermine and Sibutramine(Meridia™) should be treated as any other DEA Controlled Substance, Schedule IV drug. You may accept prescriptions for Phentermine and Sibutramine from an appropriate prescriber by phone, fax, or in writing. Phentermine and Sibutramine may be refilled in strict conformity with dosage directions up to the number of refills indicated or up to a maximum of five refills within a period of six-months from the time the prescription was issued.